
PHARMACEUTICALS
Nopras
TECHNOLOGIES, INC
Our People Speak **Compliance**
Are **Driven** By Innovation
And **Passionate** About What We Do

Nopras Technologies, Inc., is a full-service consulting company providing regulatory consulting services to the global pharmaceutical, biologics/biotechnology and medical device industries. Our staff includes experienced technical, quality, and compliance experts from industry leaders. The officers and employees of Nopras Technologies, Inc. offer a comprehensive knowledge of FDA and quality auditing procedures and practices and a unique awareness of regulatory enforcement policies and activities.

At Nopras Technologies, we believe that tremendous synergy comes from having experienced, senior level personnel from industry. Our experience also gives us a broad and detailed understanding of the complex business and compliance challenges faced by today's regulated companies.

PHARMACEUTICALS

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There are a myriad of challenges facing the pharmaceutical industry; from mergers and acquisitions to globalization and increased government scrutiny of regulatory compliance. Constant pressure to increase quality and safety while reducing the cost of drugs continue to compound these challenges. Nopras Technologies helps companies searching for ways to reduce cost and increase efficiency without compromising compliance with laws and international government regulations. Our service portfolio spans US FDA and foreign regulations and guidelines. Our experience spans the drug development life cycle, from clinical development to post-marketing scrutiny. Our consultants possess knowledge and extensive experience with cGMP, GLP, GCP and international guidelines such as ICH, and GAMP. Our knowledge of quality standards is paramount to our work on quality systems with our clients.

Nopras Technologies services for the Pharmaceuticals Industry include:

- *Program Design*
- *Operational Excellence*
- *Regulatory Preparation and Submission*
- *Drug Development Support*
- *Validation Consultation*
- *Operational Support*
- *Validation Protocol Development and Execution*

PROGRAM DESIGN

We support a team structure that is focused on the goals and milestones of our clients and achieved through close communication, detailed measurement and tracking. Nopras will build flexibility into your development strategy for risk mitigation and work with you to provide seamless communications.

- Preparing gap analysis
- Designing, executing and managing integrated development plans
- Controlling cost to agreed budgets

OPERATIONAL EXCELLENCE

In an ever changing marketplace, it takes consistency and discipline to keep everyone aligned. At Nopras Technologies, Inc, our Process Management Team will assist you to automate, manage and evolve processes to optimize performance and increase the bottom-line. From streamlining business activities contained within a single department to processes that cross your entire organization, our Process Management Team of experts will help your organization work smarter. We will help execute business processes with speed and consistency–ensuring that your organization doesn't just survive, it thrives!

- Operating Costs Reduction
- Capital Expenditure Minimization
- Scaling Production to Demand
- Production Efficiency Improvement and Cycle Time Reduction
- Quality Improvement
- Process Capability and Control (PC&C)
- Six Sigma Methodologies Implementation.

REGULATORY PREPARATION AND SUBMISSION

Nopras Technologies, Inc can guide you through the complicated regulatory environment associated with product development and registration. Our team of experts have extensive regulatory experience with the US FDA, EMEA, JPAL and Health Canada. We will assist you in making sound business decisions by providing proper understanding of the potential regulatory risks before they become major regulatory roadblocks. Our team of experts have a strategic regulatory focus with attention to the challenges in the pharmaceutical, medical device and biologic/biotechnology industries. Nopras Technologies team of experts employ critical thinking to identify and resolve problems in a proactive and innovative manner.

- Regulatory submission oversight, management, preparation & maintenance (U.S., Canada, Japan & E.U.)
- IND's, IMPD's, CTA's or individual dossier components
- NDA's, ANDA's, NDS' and MAAs in CTD format or individual dossier components
- CMC- specific: IND, IMPD, NDA, ANDA, NDS, MAA, MDF/EDMF
- Preparation of regulatory submission technical sections and summaries
- Orphan drug designation applications
- Regulatory compliance gap analysis of product development plans and submissions
- Design/Review of preclinical pharmacology/toxicology studies
- Development of Clinical Development Plans (CDP); clinical protocol and investigator brochure development / review
- Clinical study Request for Proposal (RFP) preparation

DRUG DEVELOPMENT SUPPORT

Our consultants offer a level of experience unmatched in the industry and provide exceptional process, technical, and regulatory support:

- From small molecules and vaccines to biologics.
- Gap analysis & regulatory/scientific product assessment
- Strategic advice on development
- Guidance on interactions with regulatory agencies
- Technology transfer
- Analytical methods development
- Process development and formulation development

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VALIDATION CONSULTATION

- Design Review/Qualifications
- Validation Master Planning
- 21 CFR Part 11, Electronic Records/Electronic Signature Compliance
- Validation Implementation Planning
- Validation Policies and Procedures
- Validation Training
- cGMP/Quality Systems Auditing
- Quality Systems Design, Management, Remediation
- Stability Program Design/Implementation.
- Software Supplier Audits.
- Vendor Certification Process Design & Implementation

OPERATIONAL SUPPORT

- Metrology/Calibration System Development
- Standard Operating Procedures
- Preventative Maintenance Systems
- Change Control Development and Implementation

VALIDATION PROTOCOL DEVELOPMENT AND EXECUTION

Process Development and Validation

- Manufacturing Process Development and Validation
- Process Assessment and Optimization (Design of Experiments/SPC)
- Manufacturing Scale-Up
- Technology Transfer
- Technical Report Writing (Validation, etc.)
- Equipment Qualification
- Cleaning Validation

Computer Systems Validation

- Assessment and Remediation of Manufacturing, Laboratory, Medical Device, R&D Facilities & Equipment
- Computer-Controlled - Laboratory Equipment
- Database Management Systems (LIMS, ERP, MRP, MES, EMS, Document Management) IQ, OQ, PQ Protocols

Laboratory and Analytical Support

- Analytical Method Development and Validation
- Cleaning Validation & Analytical Testing (Verification)
- Equipment Qualification (IQ, OQ, PQ)
- Stability Program Design

Manufacturing and Manufacturing Support

- Cleaning Methods Development (Cleaning Validation)
- Sterilization Cycle Development
- Process Cycle Time Reduction
- Barrier/Isolation Systems Design
- Water Systems Validation
- Aseptic Manufacturing Systems Design
- Filling and Packaging Process Design and Validation
- Documentation Systems Assessment and Remediation

Nopras TECHNOLOGIES, INC.

Nopras Technologies, Inc
39555 Orchard Hill Place
Suite 600
Novi, MI 48375
United States

Phone: (248) 341-3845
Sales: (866) 241-9913
Fax: (248) 649-5892
Email: saleshelp@nopras-tech.com